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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,939	12/29/2000	Bruce L. Gibbins	01005-0121 (41946-251368)	9231

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,939	GIBBINS ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,12 and 21-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6, 8,12 and 21-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/14/2007, and supplemental amendment and declaration filed 04/03/2007.

Claims 5, 7, 9-11, and 13-20 have been canceled.

Claims 1-4, 6, 8, 12, 21-39 are included in the prosecution.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The rejection of claims 1-4, 6, 8, 12 and 21-39 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 6, 8, 12 and 21-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to the claims to recite the limitation of: "oxygen in the closed cells is dispersed throughout the polymer network" has introduced new matter that has not been disclosed by the specification as originally filed. Nowhere in the specification applicants have disclosed that the oxygen in the closed cells is dispersed throughout the polymer network. On page 21 of the present specification, lines 10-15, applicants disclosed that the chemical reaction causes formation of oxygen that causes formation of closed cell bubbles within the matrix, wherein the cells contain an enriched concentration of gaseous oxygen. On page 26 of the present specification, lines 15-26, applicants disclosed the foam or bubbles of the present invention are formed by chemically foaming the polymer network and disclosed that the liberated oxygen becomes entrapped as bubbles formed in situ. Example 1, on page 43 of the present specification describes the preparation of oxygen containing closed cell foam device, however, nowhere the example support the newly added limitation of "oxygen in closed cells is dispersed throughout the polymer network". Therefore, applicants have no support for the limitation of "oxygen in the closed cells is dispersed throughout the polymer network". In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 6, 8, 12 and 21-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: the reactant produces oxygen that is the peroxide because oxygen cannot be produced by catalyst without oxygen source.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 1-4, 6, 8, 12, 21-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0042587 ('587) in view of US 5,792,090 ('090).

The present claim 1 is directed to a product comprises matrix of cross-linked polymer containing oxygen produced by catalyst.

US '587 teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam that can be produced chemically and contains gasses including oxygen (paragraph 0036).

However, US '587 does not teach the chemical reaction that produces the gas in the foam as claimed in claim 1. US '587 does not teach polyacrylamide polymer as claimed in claims 3 and 37.

US '090 teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises hydrogel or polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide

or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The hydrogel or foam can be guar gum or polyacrylamide and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam that can be produced chemically as disclosed by US '587, and produce the foam by oxygen gas delivered by the reaction of hydrogen peroxide and catalyst and replace the polymer by polyacrylamide as disclosed by US '090, motivated by the teaching of US '090 that such polyacrylamide polymer foam containing oxygen are optimal for minimization of infection, with reasonable expectation of having polyacrylamide cross-linked closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin.

Response to Arguments

8. Applicant's arguments filed 02/14/2007 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that the attached Declaration shows that articles made using the methods taught by the Murdock application in Examples 1 and 2 results in a polymer-based article that does not provide as much oxygen as the AcryMed matrix. The Murdock articles, made as described as Batch 1 and Batch 2, delivered oxygen at the level of only 35 mmHg and 15 mmHg, respectively, compared to the AcryMed matrix oxygen delivery at 196 mmHg. The

Figures 1-3 shows flat lines for the delivery of oxygen by the Murdock articles (Figures 1 and 2), and an essentially static release of oxygen. In contrast, the AcryMed matrix Figure 3 delivers an increasing amount of oxygen over time. Experiment 2 shows that when the same sized materials are compared, the amount of oxygen and the delivery of oxygen by the AcryMed matrix is different from that of the Murdock article. In a measure of absolute oxygen content in Table 2, the Murdock articles contained oxygen, that was released in a 24 hour period, of an average of 19.52 mmHg for Batch 1 and 4.6 mmHg for Batch 2. The AcryMed matrix contained an average of 244.15 mmHg of deliverable oxygen. The difference in amount of oxygen released for the AcryMed matrix is 12.5 times that of the Murdock article (Batch 1) and 53.1 times that or the Murdock article (Batch 2). The oxygen % of material, wt/wt, is very different for the AcryMed matrix compared to any of the Murdock articles, 0.23% and 0.37% for the AcryMed matrices compared to less than 0.0005% for the Murdock article. The look and feel of the two materials are also different. The two batches of Murdock articles, which have different freeze/thaw steps, had similar appearances and appear as gelatinous slab of polymer material with very small closed-cells within the polymer material. In contrast, the AcryMed matrix has many, regularly sized closed-cells and the majority of the volume of the material is closed cells, not polymer material. These differences are also indicated in Table 2, where a 60 mm diameter sample of both batches of the Murdock article has a weight between 5.4-6.4 grams, whereas a 60 mm diameter sample of the AcryMed matrix has a weight of 0.22-0.37 grams. After 24 hours of soaking in water, the changes to the Murdock article and the AcryMed matrix were noticeable. The Murdock article

became transparent and the structural integrity of the material was sharply decreased. The AcryMed matrix maintained its general appearance with a decrease in size of the closed-cells, and thus resulting overall size, but maintained its structural integrity.

Applicants further argue that the addition of the teachings of the '090 does not cure the deficiencies of the Murdock teaching and substitution of polyacrylamide for the methods taught in Example 1 and 2 of Murdock would lead to an article that is not polymerized because oxygen inhibits the polymerization of acrylamide. Therefore, the neither the cited references alone nor in combination do not render the currently claimed invention obvious.

In response to these arguments, applicants' attention is drawn to the scope of the present claims that is directed to a product comprising cross-linked matrix containing oxygen in closed cells. Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and closed cell containing oxygen that can be produced chemically. Cellulose derivatives read on the polymeric network claimed by applicants'. Murdock suggests chemical formation of gas in the closed cells. US '090 teaches method for chemical generation of oxygen using catalyst and peroxide that is suitable for wound dressings. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to generate oxygen into the wound dressing disclosed by Murdock using catalyst and peroxide used by US '090 because US '090 teaches oxygen reduced infection, with reasonable expectation of having cross-linked matrix containing closed cell foam entrapping oxygen produced chemically by the

reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin. One cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986).

Additionally, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding US '090, the reference is relied upon for the solely teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide. The cross-linked polymer matrix is taught by Murdock, but Murdock does not specifically teach polyacrylamide. Further, US '090 teaches advantage of dressing comprising polyacrylamide polymer and oxygen generated from the reaction of catalyst and peroxide to supply oxygen to the wound for optimal healing and minimization of infection, and this would have been motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by Murdock with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as disclosed by US '090.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require

absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Response to Amendment

9. The declaration under 37 CFR 1.132 filed 04/03/2007 is insufficient to overcome the rejection of claims 1-4, 6, 8, 12, 21-39 based upon 35 U.S.C. 103(a) as being unpatentable over US 2002/0042587 (Murdock) in view of US 5,792,090 ('090) as set forth in the last Office action because: it include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The present claims are directed to product comprising cross-linked polymeric matrix containing oxygen in closed cells, and the declaration is directed to wound dressing made of cross-linked polyacrylamide comprising closed cells containing oxygen. The scope of the claims is broad covering any article comprising cross-linked polymeric matrix containing closed cell containing

oxygen while the declaration is limited to one specific embodiment of AcryMed wound dressing made of polyacrylamide. The single and specific species of the article of the declaration does not support the generic concept of the claims. Furthermore, applicants' declaration shows superior results, but not unexpected.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

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